



WEEK ENDING DECEMBER 13, 2013

OPP Weekly Activity Report

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ANTIMICROBIALS DIVISION

Integrated Risk Information System (IRIS) Chemicals Meeting - Antimicrobials Division staff attended a bi-monthly IRIS chemicals meeting held December 12 and 13, 2013 in Potomac Yard South. The meeting provided an opportunity for public input and discussion on the draft carcinogenicity assessment for ethylene oxide (EtO). EtO is a commodity fumigant and sterilant with both antimicrobial and agricultural uses. The IRIS program released a draft carcinogenicity assessment of EtO in July of 2013 for public comment. EPA has received hundreds of pages of comments. At the meeting several recommendations from commenters (primarily ACC) were made on the draft assessment, including: (1) EPA should provide transparent discussion of criteria to classify a study as high quality and further explain why certain studies were not used (2) EPA should not combine tumor types of different origins for the assessment (3) EPA should provide discussion of how endogenous exposures to EtO are considered in the risk estimate (4) the draft assessment contains risk estimates that are unrealistically high (5) IRIS should include both a non-linear and linear assessment for carcinogenicity of EtO (5) EPA should engage other affected Federal entities and the user community. Stakeholders noted their appreciation for the opportunity to comment on the draft assessment and the upcoming peer review. NCEA announced that it plans to release a revised draft in February 2014 prior to the planned peer review. (Tim McMahon/703-308-6342 and Tim Leighton/305-7435).

AD participates in the CSPA annual Meeting. On December 11th, Susan Lewis participated in the CSPA Antimicrobial Regulatory Meeting. Topics included FY2014 priorities, the Antimicrobial Testing Program, recent performance changes to the UDM test method, coordination with California, confirmatory efficacy requirements, 810 guideline updates and OECD activities. CSPA is looking forward to our co-sponsored workshop being held in mid-February. (Susan Lewis, 308-8009)

NSF/EPA/USDA Grantees Conference on Nanotechnology. On December 4-6, 2013: AD personnel attended the conference which is a forum for Research Grantees to present their latest research on nanomaterials and nanotechnology. NSF awards a number of research grants to study the fate, transport and ecotoxicity of nanomaterials in various environmental media. The meeting was attended by government and academics. The proceedings will be posted in a report on the NSF website later. (Najm Shamim, 703-308-9445)

ENVIRONMENTAL FATE & EFFECTS DIVISION

Honey Bee Health Coalition Meeting. EFED staff participated in the Honey Bee Health Scoping meeting December 9 – 10, 2013, in Keystone, Colorado. The meeting was coordinated by the Keystone Center with funds provided by

Monsanto and the Clinton Foundation. The meeting convened a diverse set of stakeholders to discuss the potential purpose, goals and structure of a coalition of various sectors (crop production, beekeepers, agrochemical, university, non-government organizations, and government) to address factors associated with declines in honey bee health (e.g., disease, pests, nutrition and pesticides). Participants agreed that a coalition would be an effective means of addressing specific focal areas which were identified during the meeting but emphasized that success would depend on the extent to which coalition members would be willing/able to commit resources and produce measurable results within a well defined time period. (Tom Steeger, 703-305-5444).

PESTICIDE RE-EVALUATION DIVISION

Mesotrione First Team Meeting Held for Registration Review. On December 3, 2013, the first team meeting for the Mesotrione registration review was held with team members from EFED, HED, RD, and BEAD to discuss the background, anticipated data needs, and scheduling for registration review. Mesotrione is an herbicide used to treat broadleaf weeds on corn and a variety of other crops, as well as on ornamental lawns and turf. Agency first registered Mesotrione in 2001, and therefore, it is not subject to any RED mitigation. The Preliminary Work Plan and docket is scheduled to open in June 2014. (Jolene Trujillo, 703-347-0103)

PRD/EFED Meet with Bayer to Discuss Trichlorfon Risk Assessment. On December 5, 2013, PRD and EFED met with Bayer CropScience to discuss and provide feedback on their proposed refinement of environmental exposure models and the results of recently submitted wash-off/watering-in studies conducted to address risk concerns identified in the problem formulation. The current stewardship program and product labeling were also discussed. Trichlorfon is an organophosphate insecticide registered for use on nonagricultural, commercial, and residential use sites. (Garland Waleko, 703-308-8049)

EPA Meets with CMTF and Metam Task Force. On Wednesday, December 11, 2013, individuals from HED and PRD met with representatives from the Chloropicrin Manufacturer's Task Force (CMTF) and the Metam Task Force regarding the ambient air monitoring studies requested following the 2009 soil fumigant amended reregistration eligibility decisions. The task forces anticipate submitting an outline of their progress on site selection, study design, and analytical methods by the end of the month. (Dana L. Friedman, 703-347-8827)

PRD Meets with OAPTF to Discuss MSMA Registration Review Data Requirements and Turf Uses. On December 11, 2013, PRD met with the Organic Arsenicals Product Task Force (OAPTF) to discuss the Registration Review data requirements that will be issued in a forthcoming DCI. Also discussed was the extension of the

use of MSMA on golf course, sod farm, and highway rights-of-way, in light of the on-going NAS review of inorganic arsenic. MSMA is a broad-spectrum herbicide used to control grasses and broadleaf weeds on cotton, golf courses, sod farms, and highway rights of way. Residential uses were voluntarily canceled in 2009. (Garland Waleko, 703-308-8049)

FIELD & EXTERNAL AFFAIRS DIVISION

FEAD and BEAD meet with OMB and Interagency Review Team on WPS Proposals.

On Monday December 9, FEAD and BEAD participated in a conference call with interagency reviewers and OMB to discuss responses to their comments on the proposed rulemaking. Reviewers were from Department of Labor; the White House's Council on Environmental Quality; USDA's Forest Service, Office of Pest Management Policy, and the Office of the Chief Economist; OMB's Office of Information and Regulatory Affairs; and the Department of Justice, among others. Issues raised included our authority for establishing protections for children under the rule, the use of sources of income other than farming for estimating impacts, and suggestions for clarifying language. Because many reviewers were unable to participate in the conference call because of the inclement weather, OMB is gathering their reactions to forward to us next week for resolution. (TJ Wyatt, 308-7228; Derek Berwald, 308-8115; Michelle-Arling, 308-5891; Kathy Davis, 308-7002)

New SENSOR-Pesticides Fellow Presents Research findings to OPP Staff. Gamola Fortenterry, Ph.D., is the new Association of Schools and Programs of Public Health Fellow at CDC/NIOSH working with the SENSOR-Pesticides program. This fellowship is funded by EPA through the EPA/NIOSH Interagency agreement to support SENSOR-Pesticides. Gamola earned her Ph.D. in Environmental Health Sciences from the University of Michigan in May 2013. She has conducted research on urinary TCPY in pregnant women from Mexico City and the relationship with child ADHD. This paper is published online at <http://www.sciencedirect.com/science/article/pii/S1438463913001120>. Gamola presented the published study findings to OPP staff from HED and FEAD and fielded our questions. This presentation provided a nice opportunity for OPP staff to meet the new SENSOR-Pesticides Fellow. (Elizabeth Evans, 305-7891)

DCI ICR Industry Consultation Workshop Held. On December 12, FEAD and BEAD conducted a workshop with industry representatives as part of the consultation process for the Data Call In Information Collection Request renewal being prepared. Thirteen registrants and trade associations participated in the workshop via Webinar and seemed pleased with the presentations and opportunity for input. Written comments from participants are due by January 27, 2014. Earlier this year OPP and RCS negotiated a revamped approach to the DCI ICR in an effort to eliminate or streamline the process for review and approval of DCI packages by OMB prior to issuance. This workshop is a more robust consultation process than

normally used for ICR renewals, in an effort to facilitate better input by respondents and improve our burden estimates for responding to DCIs. Thanks to BEAD for a lot of hard work preparing the burden methodology documents and presenting them at the Webinar, and to PRD, AD and RCS for guidance, input and support. (J. Hogue, 308-9072).

REGISTRATION DIVISION

OPP'S Vision Workgroup 1 Meeting with Food and Drug Administration (FDA)

Medical Officer On December 4, 2013, Randy Levin, MD., Medical Officer with the Food and Drug Administration (FDA) met with members of OPP's Vision Workgroup 1 to discuss FDA's electronic-structured product labeling. Part of OPP's Direction-Setting initiative, Workgroup 1 is working toward obtaining instantaneous access to quality information to support sound decision-making across the Office. During the meeting, Dr. Levin discussed the adoption of the electronic submission process by FDA in 2009 for the drug industry and the steps they have taken to provide necessary drug safety information to the public and improve internal processes. Dr. Levin provided information on costs for implementing structured product labeling, benefits to FDA and stakeholders, and shared his thoughts on lessons FDA learned during the implementation process. The group discussed the practicalities of adopting a similar system for the Office of Pesticides Programs and ways the two agencies can work together to achieve this goal. (Maggie Rudick, 703/347-0257)

New Tolerances Established for Flonicamid On December 11, 2013, the *Federal Register* published a final rule establishing permanent tolerances for residues of flonicamid in or on alfalfa forage, alfalfa hay, alfalfa seed, peppermint tops, spearmint tops, the Fruiting Vegetable Group 8-10, Cucurbit Vegetable Group 9, the Pome Fruit Group 11-10, the Stone Fruit Group 12-12, almond hulls, the Tree Nut Group 14-12, and hog fat, meat, and meat byproducts. Also, the existing tolerance for milk was revised. The review of the tomato residue field trials was a joint review with Health Canada Pest Management Regulatory Agency (PMRA). Flonicamid is a systemic insecticide that immediately suppresses the feeding of sucking insects on plants. Based on its chemical structure (a nicotinic acid derivative), it is expected to exhibit the same mode of action as similarly-structured neonicotinoid pesticides. However, flonicamid has not been found to activate acetylcholine esterase (like organophosphates and carbamates), or nicotinic acetylcholine receptors (like neonicotinoids). Flonicamid is registered for use on a variety of agricultural crops. Interregional Research Project Number 4 (IR-4) and ISK Biosciences requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). (Andrew Ertman, 703/347-8728)

EPA and Interregional Research Project Number 4 (IR-4) Minor Use Technical Working Group (TWG) Meeting

On December 12, 2013, EPA/IR-4 Minor Use TWG

met at Potomac Yard to discuss regulatory, technical, policy, and coordination issues related to minor crops pest management. Barbara Madden (RD) chaired the meeting which included attendees and/or teleconferencing participants from EPA, IR-4, Health Canada Pest Management Regulatory Agency (PMRA), and Canada's Pest Management Centre (PMC). The morning session began with introductions followed by RD and IR-4 program overviews from Marion Johnson (RD) and Dan Kunkel (IR-4), respectively; covering relevant program activities, status updates, and priority items. Next, issues were discussed surrounding maximum residue limits (MRLs) and tolerance alignment with CODEX and improvements in communications between stakeholders to avoid trade irritants with Canada. Dana Vogel, Mike Doherty, and Kelly Lowe (HED) provided updates on EPA policies on several data requirements and defined parameters available to registrants to satisfy requirements. Bernie Schneider (HED) reported on a recent ChemSac decision--recommending classification of industrial rapeseed, high uric acid, and processed meal as an "insignificant feed" for animals. Cynthia Giles-Parker, Shaunta Hill, and Dan Rosenblatt (RD) discussed current EPA policy, an internal review panel for assessing new antibiotics, and public process requirements. Steve Schaible provided an update on requirements for reduced risk chemical classification proposals including new "stop light" tabulations requirements which provide a profile of known risks posed by the subject chemical. Beginning the afternoon session: Lois Rossi (RD) discussed points of interest from the recent NAFTA meeting with particular emphasis on MRL harmonization and the importance of effective global coordination toward achieving that end; Laura Nollen (RD) provided an update on the status of Phase IV of the Crop Group rule; Bernie Schneider and Bill Barney (IR-4) reported on the progress of future crop grouping provisions; Susan Wong (PMRA) and Shirley Archambault (PMC) and gave progress reports on the completion of action items from the U.S.-Canada Regulatory Cooperation Council; Susan Wong provided an overview and highlights of a successfully-completed pilot project and planned implementations for program improvements; Peter Caulkins (OPP/IO) and Jerry Barron (IR-4) discussed issues and concerns regarding OPP's implementation of the revised Public Interest Finding (PIF) for the IR-4 exemption under PRIA III; and Van Starner (IR-4) proposed several potential locations and dates for an IR-4/EPA Crop Tour which would immediately follow the next scheduled TWG meeting in June 2014. (Sidney Jackson, 703/305-7610)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
The Fungicide Branch granted:					
Chloropicrin	Trical Inc.	11220-410	R300	12/13/2013	12/12/2013
Erin Malone, 703/347-0253					
The Herbicide Branch granted:					
2,4-D,2-ethylhexyl ester	PBI/Gordon Corporation	2217-989	R300	11/15/2014	12/11/2013
2,4-D, dimethylamine salt	Makhteshim Agan of North America, Inc.	66222-225	R340	12/5/2013	12/11/2013
Penoxsulam	PBI/Gordon Corporation	2217-990	R300	11/15/2013	12/11/2013
Dianne Morgan, 703/305-6217					
2,4-D, dimethylamine salt	Control Solutions, Inc.	53883-334	R340	12/5/2013	12/6/2013
Grant Rowland, 703/347-0254					
The Insecticide Branch granted:					
Gamma-Cyhalothrin	Cheminova, Inc.	67760-122	R310	12/2/2013	12/12/2013
Melody Banks, 703/305-5063					
The Insecticide-Rodenticide Branch granted:					
Polybutene	Jeonjinbio Col, Ltd.	88080-2	R334	12/18/2013	12/11/2013
Jennifer Gaines, 703/305-5967					
Imidacloprid	Bayer Advanced	72155-72	R340	12/16/2013	12/12/2013
Autumn Metzger, 703/305-5314					
R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackaging of registered end-use or manufacturing-use product that requires no data submission or data matrix ^{(2) (3)} ; R310 – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging ^{(2) (3)} ; R334 – New product; MUP or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation ^{(2) (3)} ; and R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements) ^{(2) (3)}					

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

BPPD Hosts Quarterly Meeting with Biopesticide Industry Alliance. On December 11, BPPD met with the Regulatory Committee of Biopesticide Industry Alliance (BPIA), which represents a majority of the Division's biochemical and microbial pesticide producers. The agenda included a pilot project under the "Design for the Environment" program in place for chemicals, communications, bee studies, tolerances for biopesticides, and registration review updates. BPIA also provided highlights and participant comments from a recent biopesticide regulatory training workshop held during its semi-annual meeting in early October. BPPD was originally scheduled to participate in the workshop, but the partial government shutdown intervened. (Sheryl Reilly, 308-8269)

MPB Meets w/ PMRA and BASF for Joint Review Presubmission Meeting.

On December 13, MPB staff met with Health-Canada PMRA staff and BASF to discuss data requirements for a joint review of a new microbial active ingredient to be used in greenhouses. Application packages from BASF are anticipated in early 2014. (Gail Tomimatsu, 308-8543)

EPA Holds SAP on Corn Rootworm Resistance Monitoring.

On December 4 - 5, the EPA FIFRA Scientific Advisory Panel (SAP) met to consider and review issues related to the *Scientific Uncertainties Associated with Corn Rootworm Resistance Monitoring for Bt Corn Plant Incorporated Protectants (PIPs)*. BPPD presented a white paper and six charge questions to the SAP that contained the Agency's analysis and recommendations to improve resistance monitoring in Bt corn for corn rootworm. The Agency asked for scientific feedback on BPPD's proposed changes to the current sampling schemes, assay methodology, resistance definitions and remedial action approaches. The panel supported EPA's conceptual goal to design a more proactive plan that would assist in the earlier detection of resistance events. The panel recommended that an IPM approach be taken "up front" for the corn rootworm toxins – i.e., before resistance problems occur in the field. Their preferred IPM strategies involved rotation to a non-host crop (soybean), planting of non-Bt corn with or without insecticide use (i.e., conventional corn), and Bt corn with no unnecessary insecticide treatments. Additional info available at <http://www.epa.gov/scipoly/sap/meetings/2013/120413meeting.html>; Panel member roster: <http://www.epa.gov/scipoly/sap/meetings/2013/december/120413panel.pdf>. (Jeannette Martinez, 305-1016; Alan Reynolds, 605-0515)

HEALTH EFFECTS DIVISION

Meeting Between CropLife America, PMRA, and OPP on Using Toxicokinetic Data in Risk Assessment:

On December 5, scientists from HED attended a conference call with scientists from PMRA and CropLife America to discuss the use of toxicokinetic (TK) data in risk assessment. Short, introductory presentations were given by each organization followed by engaging group discussion. The focus of the discussion was primarily on TK for use in dose selection. A follow up meeting will be scheduled for January, 2014 to continue discussions. (Anna Lowit, 308-4135; Elizabeth Mendez, 305-5453)

HED Veterinarian Attends the Annual Colonial Veterinary Conference in Williamsburg, VA:

HED's RAB IV toxicologist and veterinarian Ayaad Assaad attended the 2013 Annual Colonial Veterinary Conference in Williamsburg, VA December 4-8, 2013. The conference covered a wide range of topics in both veterinary basic and clinical sciences. Lectures of importance to our animal studies included canine joint diseases, nutritional management of canine gastrointestinal disease, diagnosis and management of skin diseases in dogs,

allergy testing – *in vitro* (serum) testing vs. *in vivo* (intra-dermal testing), diagnosis and management of cardiac disorders in dogs, hypertension, reading and interpreting thoracic radiographs and electro-cardiograms, an overview of the pathology underlying many of animal diseases discussed in the conference. The conference is designated as 20 CME hours by the American Veterinary Medical Association for licenses renewal. (A. Assaad, 305-0314)

Conference Call On Modeling Issues and New Jersey Fumigation Facility: OPP staff from PRD and HED participated in a conference call (12/3) with SCS Engineering, a local consulting group, representing the Western Fumigation Company and an attorney from Western Fumigation. The issue which was discussed focused on a requirement by the New Jersey Department of Environmental Protection (NJDEP) for a Title 5 Permit Application for modeling emissions after methyl bromide fumigations at the port of Gloucester NJ. The major use at that port is fumigation of Chilean grape imports. NJDEP requires that the AERMOD model be used and the discussion focused on the Agency use of the PERFUM model and how it could be used in this circumstance. Agency staff essentially provided background information on the PERFUM model & how it was used in the risk assessment for methyl bromide. There could be potential follow up with NJDEP should they require further information. (Jeff Dawson 305-7329)

AHETF JRC Meeting: HED staff participated in a meeting with the Joint Regulatory Committee of the AHETF (Agricultural Handlers Exposure Task Force) on December 10th. Staff from California DPR and Canada's PMRA also participated. Several topics were considered including the development of unit exposure estimates for seed treatment uses; use information for seed treatment risk assessments; an update of ongoing field studies; development of research plans for all granular product use scenarios and soil incorporation of liquid sprays; updates to the AHETF electronic database to a web-based system; timelines for completing research and reporting efforts (tentative schedule is late 2017/early 2018). Many action items were identified and follow up collaboration/work share possibilities were discussed with DPR and PMRA. (Jeff Dawson, 305-7329 and Jeff Evans 305-7877)

OPP Meets with Fumigant Task Force Members: On Wednesday December 11th, Shalu Shelat and Jeff Dawson (HED RABVI) along with PRD, met with members of the Metam Task Force, the Chloropicrin Manufacturers Task Force, and representatives from associated fumigant and legal counterparts to discuss the progress of the Ambient Air Data Call-in that was initiated as part of the Reregistration process. A timeframe for next steps and deliverables for site selection criteria, analytical methods, and study design was proposed. OPP will continue to work with the respective Task Force groups to ensure that a comprehensive study will be completed. (Shalu Shelat, 347-8660)

OPP Meets with USDA on Methyl Bromide Section 18 Registration: On Monday, December 9th, OPP representatives from RD, PRD, BEAD, and HED (Matt Lloyd, Jeff Dawson, Jack Housenger) met with representatives from the USDA APHIS Plant Protection and Quarantine team to discuss the Section 18 full quarantine exemption. HED detailed findings of the September 2013 Section 18 risk assessment (no objections to supporting the recommended tolerances, acute and chronic dietary risk estimates below the Agency's level of concern), and discussed ways to address bystander risk concerns from fumigating post-harvest commodities. EPA and USDA agreed to work closely to help investigate risk mitigation options & to keep open lines of communication. (Matt Lloyd, 308-0130)

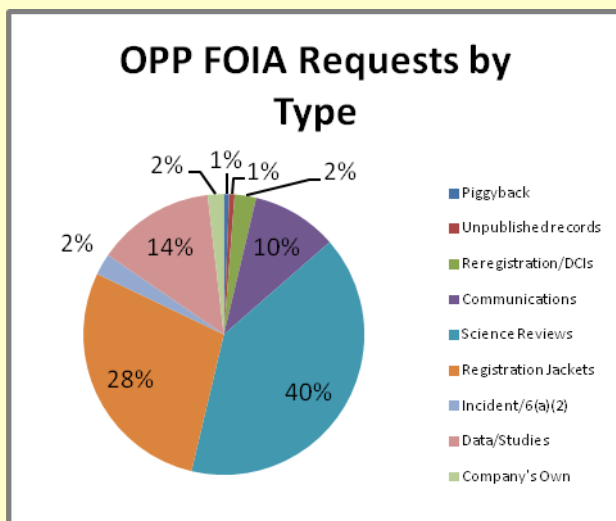
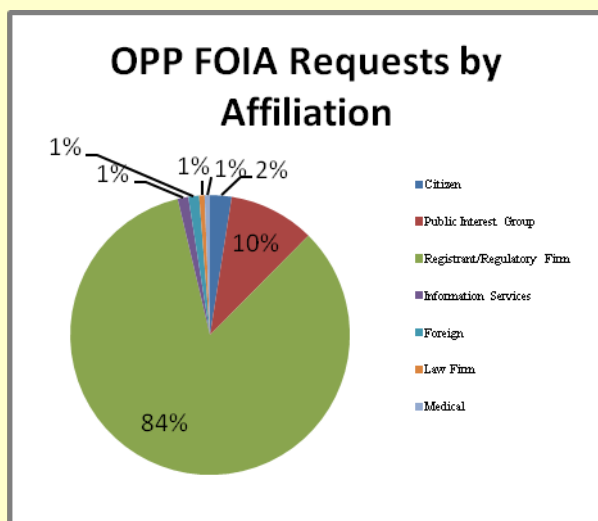
INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

Label Statement Pilot Program Web Page Published. The ITRMD Web Team worked with Claire Gesalman, OPP Communication Advisor, to publish the web page on the Label Statement Pilot Program to Help Promote Environmental Sustainability. This is a pilot project ending May 3, 2015. It allows certain statements that help promote environmental sustainability on qualifying pesticide product labels. For more information, please visit <http://www.epa.gov/pesticides/regulating/Labels/fact-statement.html>. (ITRMD Web Team, 703-605-0564)

Update to the Antimicrobial Policy & Guidance Documents. The ITRMD Web Team worked with AD to update the Registration Policy Documents web page on the Pesticides website. The Guidance/Guidelines page has a new document titled Lower Certified Limit Testing Guidance Document and can be found at: <http://www.epa.gov/oppad001/regpolicy.htm> (Carol Cotton, 703-305-5082)

OPP FOIA Activity FY13 – 4th Quarter

OPP received 160 FOIA requests during 4th Quarter FY13 and closed 134 requests. Incoming requests continued to be down markedly from the FY12 pace.





OPP FOIA Request Status Report – Dec 2- 6, 2013



<i>Requests Received</i>		<i>Requests Closed</i>			<i>Requests Open</i>		
<i>FY14</i>	<i>This Week</i>	<i>FY14</i>	<i>FYTD</i>	<i>This Week</i>	<i>FY14</i>	<i>Prior Years</i>	<i>Total</i>
82	6	17	50	13	65	290	355

(Ana Espinoza, 703-347-0102)

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

Seminar on Bioaerosol Decontamination. On December 11, Mr. Brian Heimbuch, a senior bioaerosol scientist at Applied Research Associates, Panama City, FL, presented a seminar sponsored by the Microbiology Laboratory Branch (MLB) entitled “Bioaerosol Science and Decontamination Research.” Mr. Heimbuch presented several case studies on biological aerosol research that relate to air sanitizers. Currently, no standard test methods are available for evaluating the effectiveness of antimicrobial pesticides to temporarily reduce airborne pathogens. Mr. Heimbuch discussed efforts at ASTM International to address these deficiencies and provided comments on existing Agency guidelines for testing air sanitizers. Scientists from MLB, ACB and OECA participated in the seminar. (Jafrul Hasan, 410-305-2657)

BEAD Attends Behavioral Economics Seminar. On December 5, EPA’s National Center for Environmental Economics hosted a seminar for EPA economists and staff on behavioral economics that delved into the implications of behavioral economics on program design and benefit-cost analysis. Professor Paul J. Ferraro (Georgia State University) presented his current research activities that focus on the design and evaluation of environmental policies, including social norm-based environmental programs. Professor Jason Shogren’s (University of Wyoming) presentation focused on understanding behavioral anomalies that have been and should be explored within the literature on nonmarket valuation. Much of the discussion focused on whether or not this type of “choice” architecture is relevant to measuring responses in a market context. That is should the responses be taken at face value or should researchers employ “bias-adjusting” of VSL values that are derived from markets. (TJ Wyatt, 703-308-7228 and Stephen Smearman, 703-308-8113)